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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/829,382	04/09/2001	H. Robert Masure	600-1-158N DIV	4666

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EXAMINER
MOSHER, MARY

ART UNIT	PAPER NUMBER
1648	7

DATE MAILED: 02/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/829,382	Masure et al
Examiner	**Art Unit**
Mosher	1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *10/15/02*.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *13-18, 28, and 33-72* is/are pending in the application.

4a) Of the above, claim(s) *13-18, 28, 33-40, and 63-72* is/are withdrawn from consideration.

5) ☒ Claim(s) *48-54* is/are allowed.

6) ☒ Claim(s) *46 and 55-62* is/are rejected.

7) ☒ Claim(s) *41-45 and 47* is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

Applicant's election of group VII, claims 41-62, drawn to nucleic acids encoding cbp112 protein (cpbA, spsA, PspC) in Paper No. 6 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 13-18, 28, 33-40, 63-72 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 6. Claims 41-62 have been examined to the extent that they read upon the cbp112 nucleic acid.

Claim Rejections - 35 USC § 112

Claim 46 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 46 is drawn to any oligonucleotide capable of screening for a nucleic acid encoding the same product as Claim 41. Claim 41 describes the nucleic acid mainly in terms of the functional characteristics of the protein, and also requires that the protein comprise the structure of SEQ ID NO:1, a small oligopeptide. Claim 41 therefore is drawn to nucleic acids with large amounts of undefined structure. Therefore it is not possible to determine which oligonucleotides

are capable of screening for the undefined structure, and it is not possible to determine the metes and bounds of the oligonucleotides encompassed by this claim.

Claim 46 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As discussed above, claim 46 reads upon oligonucleotides of undefined structure. Because the specification fails to present the full structure of all of the proteins which have the characteristics recited in claim 41, the specification does not reasonably convey possession of the full scope of the oligonucleotides encompassed by claim 46.

Claim 62 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim is drawn to nucleic acids which hybridize to SEQ ID 20 or 24 under "highly stringent hybridization conditions." However, the specification does not contain a definition of "highly stringent" conditions. Since the precise stringency conditions affect which nucleic acids will hybridize, the scope of the claimed subject matter is indefinite.

Claim Objections

Claim 57 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Parent claim 55 is drawn to a nucleic acid encoding a fragment of a

protein. Claims 56 and 57 elaborate upon the characteristics of the protein (not necessarily the characteristics of the fragment). Claim 57 requires that the streptococcal binding protein comprises one or two lectin binding domains. Since parent claim 55 already requires that the protein comprises SEQ ID NO:25 (or a conservative amino acid substitution), the number of lectin binding domains is already fixed by the structure of SEQ ID NO:25. Is the intent actually to require that the claimed N-terminal *fragment* comprise one or two lectin biding domains?

Claims 41-46 are also objected to because they are drawn in part to subject matter which was nonelected for examination.

Priority

Applicant is denied the benefit of priority application 60/016,632 for claims 41-62, because it fails to contain an adequate written description of the nucleic acids currently claimed.

Claims 41-45 and 47-54 are directed to "An isolated nucleic acid encoding a streptococcal choline binding protein" with various structural and functional characteristics recited in the claim. The priority document describes physical characteristics of proteins having the structural and functional characteristics recited in the claims, such as to reasonably convey that applicants possessed the proteins. However, the claims are not drawn to the proteins themselves. The priority document describes processes which could be used to obtain the coding sequences, and describes nucleic acids encoding *fragments* of the proteins (up to and including SEQ ID NO:20 and 21), but the priority document nowhere describes a full coding sequence in

sufficient detail as to reasonably convey that applicants possessed a nucleic acid sequence "encoding a streptococcal choline binding protein" at the date of the priority application.

In addition, claim 46 is denied benefit; although the priority application describes some oligonucleotides within the scope of the claim, absent description of a full coding sequence the priority document cannot describe the full scope of oligonucleotides capable of screening for the full coding sequence.

In addition, claims 48-62 are denied benefit, because these claims recite sequences 24 or 25, which are not disclosed in the priority application.

Therefore, the effective date for the nucleic acids of claims 41-62 is May 1, 1997, the filing date of parent application 08/847,065. Note that this decision is based upon the written description requirement of 35 USC 112, first paragraph, not the enablement requirement.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 62 is rejected under 35 U.S.C. 102(e) as being anticipated by Briles et al 6,500,613. Briles discloses a nucleic acid sequence in Figure 25 which is 97% identical to SEQ ID NO:20, see the attached alignment. Although "highly stringent" conditions have not been defined, this degree of similarity is close enough to reasonably conclude that the reference DNA would hybridize however "highly stringent" was defined.

Claim 62 is rejected under 35 U.S.C. 102(a) as being anticipated by Briles et al WO 97/09994, for the same reasons as the rejection over Briles et al 6,500,613.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 55-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Briles et al US 6500613 or WO 97/09994. Briles discloses a nucleic acid cloned from strain D39, encoding a pneumococcal surface protein designated PspC. Applicant also cloned nucleic acids from derivatives of strain D39. Briles presents a sequence, with some ambiguous residues, in Figure 25, and presents amino acid sequences, with some ambiguous residues, in figures 28-29. Manual inspection of the amino acid sequence indicates that the N-terminal and C-terminal sequences from the reference closely match sequences in SEQ ID NO:25. (An amino acid alignment is not readily available to the examiner at this time, because the Briles Sequence Listing merges two separate sequences into a single entry.) It is also apparent that the reference teaches a protein which comprises a fragment of the N-terminal region, since it discloses an alpha helical region. Therefore, it is concluded that the reference discloses, with some ambiguous residues, an N-terminal fragment which is indistinguishable from the N-terminal region of a protein comprising SEQ ID NO:25 or a conservative in SEQ ID NO:25. Since the disclosure contains some ambiguous residues, it is not quite seen as anticipating the claimed invention. However, it would have been well within the ordinary skill of the art to obtain strain D39 and refine the sequence to determine the ambiguous nucleotides and amino acids. Note that claim 56 is included in this rejection; although the fragment taught by Briles does not include the full structure of SEQ ID NO:1, claim 56 does not require the claimed fragment to include SEQ ID NO:1. Briles also suggests that PspC is a protective immunogen, see column 121, lines 40-60. Therefore one of ordinary skill in the art would have been motivated to produce an expression vector to produce

the suggested protective immunogen, with reasonable expectation of success. Therefore, the invention as a whole is seen as prima facie obvious, absent unexpected results.

Claims 41-47 are not included in this rejection, because the protein disclosed by Briles et al does not include the full structure of SEQ ID NO:1.

Allowable Subject Matter

Claims 48-54 are allowed, because the prior art does not teach or suggest a nucleic acid encoding a streptococcal choline binding protein comprising SEQ ID NO:25 or a conservative amino acid substitution.

Claim 47 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 41-46 would be allowed if limited to the elected subject matter (but in that case claim 47 would fail to further limit claim 41). These claims contain allowable subject matter, because the closest prior art (Briles et al) does not teach or suggest a nucleic acid encoding a protein comprising SEQ ID NO:1.

Iannelli et al and Broooks-Walter et al (both unavailable as prior art) are cited as of interest, in reviewing the designations different laboratories have used for the CbpA protein, and in reviewing the variation of structure in different isolates.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is (703) 308-2926. The

examiner can normally be reached on Monday -Thursday and alternate Fridays from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is now (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

February 4, 2003

MARY E. MOSHER
PRIMARY EXAMINER
GROUP ~~1800~~ 1600

Seq 20 vs. Briles PCT

ID T61729 standard; DNA; 1326 BP.
AC T61729;
DT 28-OCT-1997 (first entry)
DE Streptococcus pneumoniae pspC gene alpha-helix and proline region.
KW PspC; PspA; pneumococcal surface protein; vaccine; otitis media;
KW meningitis; bacteraemia; pneumonia; Streptococcus pneumoniae; ss.
OS Streptococcus pneumoniae strain D39.
FH Key Location/Qualifiers
FT cds 517..1326
FT /*tag= a
FT /product= alpha-helix (bases 517-1112) and
FT proline-rich (bases 1113-1326) regions
FT of PspC"
PN WO9709994-A1.
PD 20-MAR-1997.
PF 16-SEP-1996; U14819.
PR 15-SEP-1995; US-529055.
PA (UABR-) UAB RES FOUND.
PI Briles DE, Brooks-Walter A, Crain MJ, Hollingshead S;
PI McDaniel LS, Swiatlo E, Tart R, Yother J;
DR WPI; 97-202002/18.
PT Streptococcus pneumoniae surface protein PspC and truncated PspA -
PT used in vaccines for protecting animals against S.pneumoniae
PT infection
PS Example 12; Fig 25; 296pp; English.
CC This sequence codes for the alpha-helical and proline-rich regions
CC of the pneumococcal surface protein C (PspC) of Streptococcus
CC pneumoniae strain D39. The alpha-helical encoding region is one
CC third the size of that of the strain EF6796 pspC gene (see T61728),
CC and a strong repeat observed in EF6797 pspC is not found in D39
CC pspC. A leader sequence is also absent. The data indicate that
CC there is variability in pspC structure. PspC and PspA polypeptides
CC can be used in vaccines for protecting animals against S. pneumoniae
CC infection.
SQ Sequence 1326 BP; 537 A; 207 C; 261 G; 291 T;

Query Match 97.0%; Score 416; DB 33; Length 1326;
Best Local Similarity 95.8%; Pred. No. 1.79e-196;
Matches 409; Conservative 10; Mismatches 8; Indels 0; Gaps 0;

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Db    779 aaaaggtagcngaagctaagaagaangttgaagaagctaagaawaaagccraggatcaaa 838
          |||||||||| |||||| ||||||| |||||||||||| ||||:|||||||:|||||||||
Qy      3 AAAAGGTAGCAGAAGCTGAGAAGAAGGTTGAAGAAGCTGAGAAAAAAGCCAAGGATCAAA 62

Db    839 aagaagaagatcgycgtaactacccaaccaatacttrcaaaacgcttgaccttgaaattg 898
          |||||||||||||:|||||||||||||||||||||:||||||||||||||||||||||||
Qy     63 AAGAAGAAGATCGCCGTAACTACCCAACCAATACTTACAAAACGCTTGACCTTGAAATTG 122

Db    899 ctgagtycgatgtgaaagttaaagaagcggagcttgaactagtaaargaggaagctmmrg 958
          ||||||:|||||||||||||||||||||||||||||||||||||||:|||||||||:::|
Qy    123 CTGAGTCCGATGTGAAAGTTAAAGAAGCGGAGCTTGAACTAGTAAAAGAGGAAGCTAAGG 182

Db    959 aayctcgagacgaggaaaaaattaagcaagcaaaagcgaaagttgagagtaaaaaagctg 1018
          ||:||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Qy    183 AACCTCGAGACGAGGAAAAAATTAAGCAAGCAAAAGCGAAAGTTGAGAGTAAAAAAGCTG 242

Db   1019 aggctacaaggttagaaaacatcaagacagatngtaaaaaagcagaagaagtagntaaac 1078
          |||||||||||||||||||||||||||||| |||||||||||||||| || |||||
Qy    243 AGGCTACAAGGTTAGAAAACATCAAGACAGATCGTAAAAAAGCAGAAGAAGAAGCTAAAC 302
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Db    1079 gaaaagcagcagaagaagataaagttaaagaaaaaccagctgaacaaccacaaccagcgc 1138
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Qy     303 GAAAAGCAGCAGAAGAAGATAAAGTTAAAGAAAAACCAGCTGAACAACCACAACCAGCGC 362

Db    1139 cggntactcaaccagaaaaaccagctccaaaaccagagaagccagctgaacaaccaaaag 1198
           ||| ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Qy     363 CGGTTACTCAACCAGAAAAACCAGCTCCAAAACCAGAGAAGCCAGCTGAACAACCAAAAG 422

Db    1199 cagaaaa 1205
           |||||||
Qy     423 CAGAAAA 429
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